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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/593,855  | 09/22/2006  | Lakshmi Prasad Dasi  | GTRC166             | 5776             |
| 6980 7590 11/04/2009<br>TROUTMAN SANDERS LLP<br>BANK OF AMERICA PLAZA<br>600 PEACHTREE STREET, N.E.<br>SUITE 5200<br>ATLANTA, GA 30308-2216 |             |                      |                     |                  |
| EXAMINER  |             |                      |                     |                  |
| DEAK, LESLIE R  |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 3761  |             |                      |                     |                  |
| NOTIFICATION DATE   |             | DELIVERY MODE        |                     |                  |
| 11/04/2009  |             | ELECTRONIC           |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### Office Action Summary

**Application No.**

10/593,855

**Applicant(s)**

DASI ET AL.

**Examiner**

LESLIE R. DEAK

**Art Unit**

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7 and 13-20 is/are allowed.
- 6) ☒ Claim(s) 8-12, 21 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 22 provides for the use of a claimed device comprising the step of providing a particular device and then using it ex-vivo. However, the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. A single claim cannot protect two statutory categories of invention—apparatus and method for its use. In the instant case, it is unclear what Applicant is attempting to protect in claim 22—a method or a device. As such, the scope of the claim is indefinite.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 8-11 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,234,203 to Bäcklund.

In the specification and figures, Bäcklund discloses the device substantially as claimed by Applicant.

With regard to claims 8-11 and 21, Bäcklund discloses the claimed device, with flow lines that comprise inlets A, C, outlets, B, D, and branches that may split flow. With regard to the claimed timing of flow merging flow rates, contents of the apparatus, and outlet location, Applicant is setting forth the intended use of the claimed apparatus. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. It is the position of the Examiner that the Bäcklund device is capable of functioning in the manner claimed by Applicant, thereby meeting the limitations of the claims.

6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,234,203 to Bäcklund in view of US 2005/0221072 to Dubrow et al.

In the specification and figures, Bäcklund discloses the method substantially as claimed by Applicant with the exception of the material the device is made from. It is well-known in the art of medical implants to form the implanted device of an engineered tissue in order to enhance biocompatibility, as taught by Dubrow. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use engineered tissue as disclosed by Dubrow in the apparatus suggested by the prior art,

since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP § 2144.07.

***Allowable Subject Matter***

7. Claims 1-7 and 13-20 are allowed.
8. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest the method of providing a flow merging device, splitting IVC and SVC flow into two branches, and rejoining the blood flow, along with the other steps of the claimed method.

***Response to Arguments***

9. Applicant's arguments filed 28 August 2009 with regard to claims 1-3 are persuasive, and the rejections have been withdrawn.
10. Applicant's arguments filed 28 August 2009 with regard to claims 8-11 and 21 have been fully considered but they are not persuasive.
11. .With regard to claims 8-11 and 21, Applicant argues that the Bäcklund device does not disclose a device to merge the inlet flows only when portions of the flows are approximately parallel to one another. However, Applicant fails to disclose the merging device in any manner other than to illustrate that the flows come together in a chamber—that is, two tubes are capable of flowing into a single tube. While the Bäcklund device may not be disclosed as operating as claimed by Applicant, the **device**

disclosed by Bäcklund comprises all the structural limitations of the device claimed by Applicant. Bäcklund discloses a tubing system with inlets A, C, and outlets B, D, connected by branches a, b, c, d, which may be selectively occluded to generate a desired flow profile (see at least column 4, lines 40-62). Applicant discloses a tubing system with inlets 20, 40, and outlets 60, 80, connected by branches 28, 32, 48, 52. Since the prior art device comprises all the structural limitations of the claimed apparatus, the apparatus as claimed by Applicant is suggested by Bäcklund.

### ***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/  
Primary Examiner, Art Unit 3761  
28 October 2009